DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 28 2012

Re: Beyaz
Docket No. FDA-2011-E-0277

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,441,168 filed by Eprova AG, under 35 U.S.C. § 156. The human drug product claimed by the patent is Beyaz (drospirenone, ethinyl estradiol, and levomefolate calcium), which was assigned new drug application (NDA) No. 22-532.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Two of the active ingredients in Beyaz (drospirenone, and ethinyl estradiol) have been previously approved for commercial marketing or use in multiple other products including Yaz (from Bayer Healthcare), Loryna and Syeda (from Sandoz Inc.) and Drospirenone/Ethinyl estradiol (from Barr and from Watson Laboratories). Our records indicate that the remaining active ingredient, levomefolate calcium, represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The NDA was approved on September 24, 2010, and notice of the approval was transmitted to the applicant by e-mail on September 24, 2010, at 4:45 pm, Eastern Time. Therefore, the filing of the patent term extension application on Tuesday, November 23, 2010, was within the sixty-day period beginning on the date the product was approved, within the meaning of 35 U.S.C. § 156(d)(1), as amended by the Leahy-Smith America Invents Act (2011).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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